INFORMATION FOR THE CONSUMER

CRINONE

(Progesterone gel, 8%)

Please read this leaflet carefully before you start to use your medicine. Keep this leaflet, you may need to read it again. It contains a summary of the information available on your medicine. If after reading this you have any questions ask your doctor or pharmacist.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

About Your Medicine

The name of your medicine is CRINONE (Progesterone gel). Its active ingredient is progesterone. Each dose of the gel contains 90 mg / dose (8% gel) progesterone.

The gel also contains the following inactive ingredients: (alphabetically listed) Carbomer 974P, glycerine, hydrogenated palm oil glycerides, light liquid paraffin, polycarbophil, purified water, sodium hydroxide, sorbic acid.

CRINONE is available in 8% strength. It is a vaginally administered, systematically acting hormone preparation. CRINONE is a smooth white to off-white gel filled into vaginal applicators for single use.

CRINONE is available in packages of 6 or 18 applicators. CRINONE gel, containing progesterone, belongs to a group of medicines called progestins.

What Your Medicine is For

CRINONE (Progesterone gel) is used for luteal phase support in induced cycles such as *In Vitro* Fertilization (IVF) cycles including oocyte donation recipients with or without functional ovaries.

Before Using CRINONE (Progesterone gel)

Tell your doctor or pharmacist if:

you are allergic to any of the ingredients listed above;

you have abnormal vaginal bleeding;

you have porphyria (congenital or acquired disorder of the biosynthesis of the red blood stain);

you have malignant disease of the breast or genital organs, or if such a disease is suspected;

you have an acute blood clot including inflammation of superficial veins (thrombophlebitis), a vascular occlusion (thormboembolic disorder), or a cerebral apoplexy, or if you have had such disease before;
you are pregnant with a dead fetus (missed abortion);
you are breast feeding;
you have liver disease, epilepsy, heart or kidney problems, or are using any other vaginal product.

After using CRINONE (Progesterone gel)

The following side effects have been reported with CRINONE: cramps, breast pain, headache, pain, bloating, nausea,vaginal discharge, somnolence, intermenstrual bleeding, vaginal irritation and application site reactions

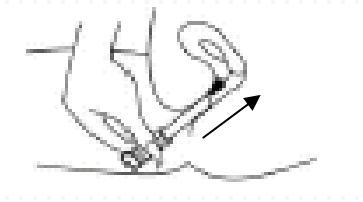
There have been occasional reports of drowsiness associated with the use of CRINONE. Therefore TAKE CARE if you intend to drive or operate machinery.

If you experience these effects and they become troublesome, please consult your doctor**.**

How to Use CRINONE (Progesterone gel)

One application of CRINONE 8% (90 mg of progesterone) every day, starting the day of the transfer. In some cases, the dose can be increased to two applications of CRINONE 8% daily. If pregnancy occurs, treatment should be continued for up to 10 to 12 weeks.

CRINONE is to be applied directly from the specially designed applicator into the vagina. CRINONE coats the vaginal mucosa to provide long-lasting release of progesterone.



Each applicator contains a slightly larger amount of gel than actually released, as the rest of the product tends to adhere to the inside of the applicator. It is therefore quite normal for a little gel to be left inside the applicator.

Each applicator contains 1.45 g vaginal gel and is designed in such way that with each administration an exactly defined amount of gel (1.125 g) is delivered. Any content of gel remaining in the applicator after use must be discarded.

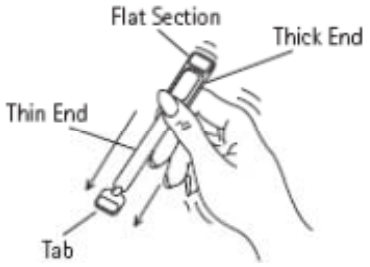
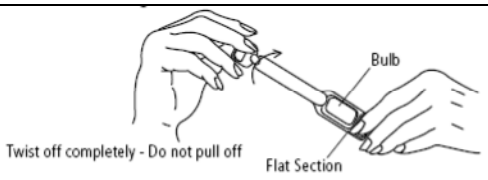
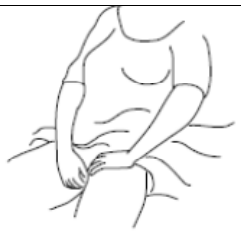
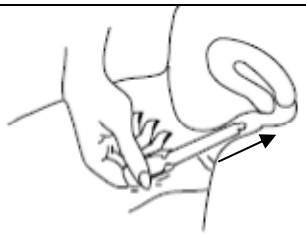
Each applicator is intended for single use only.

If you forget to use CRINONE on a normal dosage day then use it the following day and then continue as before. Do not administer double doses to make up for a forgotten single dose.

Typically the gel stays attached to the vaginal walls as the medicine absorbs. Do not be concerned if small globules appear as a discharge after several days of usage. It is common, not harmful, to have some gel residue build-up. Gel accumulation may be less likely to occur if the gel is applied in the morning because activities like walking may help spread the gel on the vaginal walls. Therefore, it is not necessary to remain lying down following administration of CRINONE. If gel accumulation becomes bothersome, talk to your doctor.

Instructions For Use

Remove the applicator from the sealed wrapper. DO NOT remove the twist-off cap at this time.

1. Grip the applicator by the thick end. Shake down like a thermometer to ensure that the contents are at the thin end.	
2. Twist-off the tab and discard.	
3. The applicator may be inserted into the vagina while you are in a sitting position or when lying on your back with your knees bent. Gently insert the thin end as far up as you comfortably can into the vagina.	
4. Press the thick end of the applicator firmly to deposit gel. Remove the applicator and discard into a waste container.	

General Things to Remember

This medication has been prescribed only for your current medical condition. Do not use it for other medical conditions.

1. Do not allow people to use your medications and do not use medications meant for other people.
2. CRINONE should not be administered simultaneously with other intravaginal therapies. If other local intravaginal therapy is to be used simultaneously, there should be at least a 6-hour period before or after CRINONE administration. Tell any doctor treating you what medications you are taking. Always carry a medical information card stating which medications you are using. This can be very important in case you are involved in an accident.
3. Make sure that other people you live with or who look after you read this information.
4. CRINONE should not be used during lactation.
5. CRINONE must not be used in children
6. Overdosage is not anticipated because each dose is applied through an individual disposable applicator. However, if it occurs, the treatment with CRINONE 8% should be discontinued.

Storage of CRINONE (Progesterone gel)

CRINONE gel should be stored at room temperature (15-25ºC) and not exposed to extreme heat or cold. As with all medicines, the gel applicators should be kept in a safe place where children cannot reach them.

Do not use CRINONE gel after the expiry date, which is printed on the label.

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